REMARKS

The Examiner has rejected claims 1-8, 10, 11, 13-18, 20, and 21 under 35 USC 103(a) as being unpatentable over VESANOID (from the Physician's Desk Reference) in view of U.S. 5,656,289 to Cho, et al.

The present invention is directed to a capsule for oral delivery of an active agent and, as set forth in the independent claims 1 and 13, includes a non-emulsified homogeneous mixture which is encapsulated by a capsule shell. It is important to understand that the invention is not directed to an emulsion, but in fact, a non-emulsified homogeneous mixture.

This mixture self-emulsifies with active agent after introduction into a gastrointestinal tract.

The VESANOID reference does not teach emulsification as acknowledge by the Examiner.

The Cho, et al. reference relied on by the Examiner teaches a pharmaceutical composition which is emulsified.

As stated by the Examiner: "The Cho, et al. patent teaches an orally administratable formulation of a biologically active material comprises a water-in-soil emulsion" (See abstract) (emphasis added).

Accordingly, there is no teaching, suggestion, hint or other reference to a capsule system in which an active

ingredient is contained in a capsule means as a non-emulsified mixture. In the present invention, the capsule shell opens upon ingestion, and thereafter, emulsification of the vehicle with the active agent dissolved therein, occurs in the intestinal tract.

Clearly, the Cho, et al. reference teaches away from this capsule system in accordance with the present invention. Since the Cho, et al. reference does not include any structure such as an emulsifies for promoting self-emulsification in the active agent and vehicle in the gastrointestinal tract and a capsule cell for encapsulating the active ingredient and emulsifier as a non-emulsified homogenous mixture there within, the Examiner has not established a prima facie case of obviousness under 35 USC 102(a).

Accordingly, the Applicants submit that since the Examiner has not made a prima facie case of obviousness, the Applicant respectively requests the Examiner to withdraw the rejection of claims 1-8, 10, 11, 13-18, 20, and 21 under 35 USC 103(a).

The Examiner has also rejected claims 1-8, 10-18 and 20-22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,248,354 and claims 1-9 of U.S. Patent No. 6,656,500.

The Applicant in order to overcome this rejection submits terminal disclaimers in favor of U.S. 6,248,354 and

6,656,500. A check in the amount of $260.00 is included for the disclaimer fees.

In view of the arguments set forth, it is submitted that each of the claims in the application defined patentable, subject matter not anticipated by the art of record and obvious to one skilled in this field who is aware of the references of record. Reconsideration and alliance and respectively requested.

Respectfully submitted,

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